ISSN 2364-2351 | A 60711 | BIOCOM

European Biotechnology

Life Sciences and Industry Magazine

Winter Edition 2021 | Volume 20 | 20 €

Interview

LSP partner Joachim Rothe on his firm's acquisition by EQT and impacts on European biotech.

FREE EXCERPT

Pandemic justice

Climate Change
What biotech has to offer in the fight against global warming

COVID-19 Meds
The power of therapeutics to change outcomes for patients

Gene & Cell Therapy
Improvements could mean a breakthrough for ATMPs

BioFairs Compass
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Building on the advances made during the pandemic

DR STEVE ARLINGTON, President of Pistoia Alliance since 2015, has over 40 years' experience in the pharmaceutical and diagnostics industry. He began as a research scientist in immunology, developed and launched many products in this arena – including Clearblue pregnancy tests. Steve led the Pharmaceutical Team at PWC and then the IBM Life Sciences and Pharmaceutical Global Teams. Steve has grown two, billion-dollar consultancies and launched a biotech company; he has also served on the advisory boards of major pharma companies.

The pharmaceutical industry has made significant advances in collaboration over the past two years, and I have seen many examples amongst Pistoia Alliance members of the power of cooperative working. It is imperative that the industry continues to build on these successes. At the same time, digital transformation has accelerated rapidly during the pandemic, which in turn has greatly improved remote patient monitoring, rapid online triage of patients, and the sharing of data. I am now urging organisations to take advantage of these new opportunities and not to let old behaviours return to slow down progress. We can continue to innovate solutions that directly benefit patients when we work together.

I am also keen to see the sector redouble its efforts in areas where progress has remained slow. While we have made incredible scientific gains to address COVID-19, there are still many diseases where little has progressed in recent decades, in terms of both treatments and outcomes for patients. For instance, one devasting disease we need to urgently address is pancreatic cancer. Currently, the combined five-year survival rate of pancreatic cancer is just 5% to 10%. Research is the key to improving this outlook and, critically, improving early diagnosis.

Collaboration will also be essential to tackling the public health issues that are set to impact society in significant ways in the coming years. Organisations must continue to work together to develop new therapies in areas such as dementia, for instance, one of the biggest challenges facing humans today. Society is now considering how we care for an ageing population and efforts must be focused on tangible steps that we can take to improve outcomes. This will involve cross-discipline partnerships that bring together innovations in technology and healthcare, as well as working closely with stakeholders in governments and regulatory authorities. By addressing pre-existing hurdles to cooperative working that hinder progress, we can enable progress in the life sciences at the same pace as has been achieved in developing COVID-19 vaccines.

The industry also needs to improve access to real-world patient data for use in R&D and put in place infrastructure that will enable safe data sharing. Many people have been understandably concerned about sharing personal information, but to enable big breakthroughs in areas like cancer and precision medicine, we all need to altruistically share our data for the greater good of research. The biopharmaceutical sector has done a lot during the pandemic to rebuild public trust in the industry. It now needs to take that even further to educate the public on the importance of data sharing, including the benefits of sharing their anonymised patient data.

At the Alliance, which currently has over 150 members, we provide members with a legal framework to enable straightforward and secure pre-competitive collaboration. ■

Pictures: Pistoia Alliance

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COVER STORY

Who's to blame for pandemic inequities?

Should developers of novel pandemic drugs, vaccines and diagnostics forgo protected rewards for their work, and allow that economic holiest of holies – exact production processes for platform technologies with multiple future applications – to be revealed to potential imitators? As the pandemic rages on, over 100 countries have said 'yes' to temporarily abolishing COVID-19-related intellectual property to try to ensure better access to medicines. Europe's last opponent, Germany, is wobbling. But would the move really mean more vaccines and new drugs?

INSIGHT EUROPE

ECONOMY

REGIONAL NEWS

SCIENCE & TECHNOLOGY

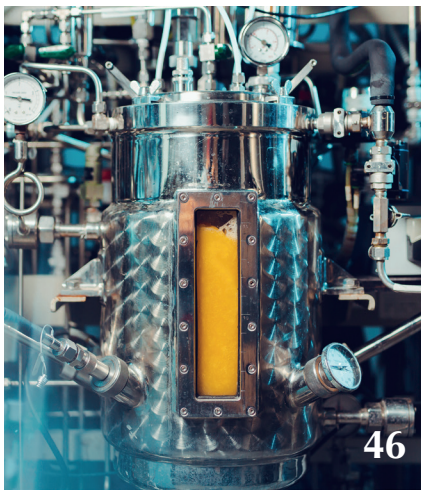
PICK & MIX

IMPRINT European Biotechnology (ISSN 2364-2351) is published quarterly by: BIOCOM AG, Jacobsenweg 61, D-13509 Berlin, Germany, Tel.: +49-30-264921-0, Fax: +49-30-264921-11, Email: service@european-biotechnology.com, Internet: www.european-biotechnology.com; Publisher: Andreas Mietzsch; Editorial Team: Thomas Gabrielczyk (Editor in Chief), Derrick Williams (Co-editor), Georg Kääb, Uta Mommert; Sandra Wirsching; Maren Kühr; Advertising: Oliver Schnell, +49-30-264921-45, Christian Böhm, +49-30-264921-49, Andreas Macht, +49-30-264921-54; Distribution: Lukas Bannert, +49-30-264921-72; Graphic Design: Michaela Reblin; Production: Martina Willnow; Printed at: Königsdruck, Berlin; European Biotechnology Life Sciences & Industry Magazine is only regularly available through subscription at BIOCOM AG. Annual subscription BIOCOM CARD Europe: €80 for private individuals (students €40) incl. VAT, €120 plus VAT for corporates. Prices includes postage & packaging. Ordered subscriptions can be cancelled within two weeks directly at BIOCOM AG. The subscription is initially valid for one year. Subscriptions will be renewed automatically for one more year, respectively, unless they are cancelled at least six weeks before the date of expiry. Failures of delivery, which BIOCOM AG is not responsible for, do not entitle the subscriber to delivery or reimbursement of pre-paid fees. Seat of court is Berlin, Germany. As regards contents: individually named articles are published within the sole responsibility of their respective authors.

CLIMATE CHANGE

(Bio)roads to zero

COP26 agreements won't solve much on their own. Reaching emissions goals will require plenty of help from biotechnology, and the sector is pursuing many different innovative paths to achieve net zero. A wide range of products can be made from captured atmospheric CO_2, and investors have gone keen on green. But there are still plenty of challenges to overcome.



NEUROTECHNOLOGIES

EQT swallows LSP

There's always a bigger fish out there. But all that will change for LSP is it'll have improved access to more financial backing. LSP just closed the largest European life sciences fund with around €1bn. The €450m acquisition deal isn't even that large in what's now a €60bn universe. We spoke with Joachim Rothe.

Pictures: LSP; Brazhyk-Elfranckito - Freepik.com; BIOCOM AG

SPECIAL

Biofairs Compass

EDITORIAL

A new world order

Two issues of global importance continue to dominate public discourse – the immediate threat posed by the ongoing COVID-19 pandemic and the more looming one posed by climate change. Together they are already causing millions of deaths and impacting billions of lives, particularly in the Global South. To avert even worse consequences from either will require international cooperation, the end of neo-colonial economic relations and equal access to technological resources, including biotechnology.

Biotech's role in the fight against SARS-CoV-2 is obvious. Diagnostics, vaccines and, more recently, promising medicines have been developed and approved at lightning speed. But biotechnological solutions that can contribute to CO_2 reduction are more small-scale, and sometimes meet with resistance. Our report on p. 44 looks in-depth at some of the solutions that start-ups and bigger players in the field of climate-mitigating technology are pursuing, especially the projects that have drawn notice from politics.

Equitable distribution of pandemic vaccines and medicines, on the other hand, has been a stumbling block that could accelerate the emergence of new virus variants. Our cover story looks at the key role cooperation between developers and politicians plays in the quest to prevent that, and distribute resources fairly.

Thomas Gabrielczyk
Editor-in-Chief

The many layers of pandemic justice

COVID-19 On the one hand, Pfizer has so far chosen to keep the recipe for its blockbuster mRNA vaccine (co-developed with BioNTech) a secret. But on the other the US pharma giant is effectively giving away the recipe for its potentially breakthrough COVID-19 therapy Paxlovid. What's the difference? And do the politicians responsible for the fair distribution of pandemic drugs worldwide understand the motives behind it?

Pfizer CEO Albert Bourla recently corrected his company's outlook on sales of Pfizer/BioNTech's mRNA-based COVID-19 vaccine Comirnaty for 2021 from US$33.5bn up to US$36bn. But when it comes to lifting the patents on the historic biotech bestseller to allow African generics producers to make them, he has refused – and with good reason. "Entities with little or no experience in manufacturing vaccines are likely to chase the very raw materials we require to scale our production, putting the safety and security of all at risk," he says. If Bourla is to be believed, Pfizer will deliver 2.7 billion doses in 2021 alone, 40% of them in middle to low-income countries. The former pay half the price wealthy countries do, the latter the cost price ($4/dose). Many will also receive donated vaccine from the World Health Organization's COVAX Initiative. That all sounds great, but so far, the entire continent of Africa has received only about as many doses as have been injected in Switzerland. And most of them came from other manufacturers.

"We deployed $2bn before we knew if we could successfully develop a vaccine," explains Bourla. "In record time, we developed the most efficient production machine for a life-saving vaccine the world has ever seen. To date [by May 2021], we have delivered about 450 million doses, and the balance is more favourable to high-income countries." Why is that? According to Bourla, Pfizer "approached all countries and asked them to place orders so that we could allocate doses to them." In reality, high-income countries reserved 70% of the available supplies. However, on December 3rd, member states in the World Trade Organisation (WTO) want to decide on a temporary patent waiver for the drugs, vaccines and diagnostics needed to fight the pandemic (see interview p. 16). The idea sounds both radical and catchy. After all, suspending patent protection for COVID-19 vaccines and medicines might help ensure that enough vaccine reaches poor countries. The so-called TRIPS (Trade-Related Aspects of Intellectual Property Rights) waiver was proposed by India and South Africa last autumn. They argued that suspending patent protection to allow products to be produced locally would help eliminate inadequate supplies in the Global South, especially supplies of COVID-19 vaccines.

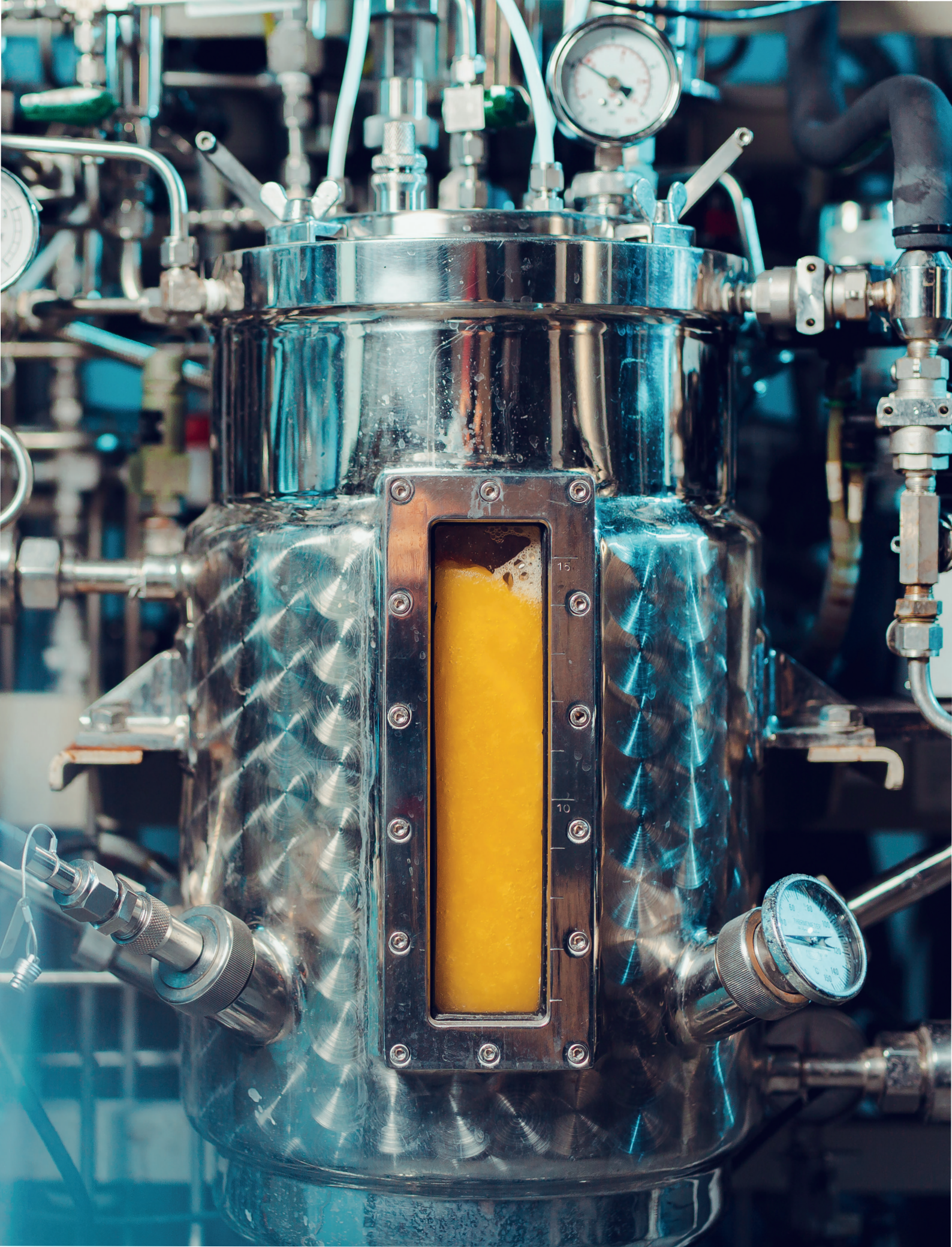
JEREMY LEVIN **CEO & Chairman, Ovid Therapeutics Inc., former Chairman BIO – Biotechnology Innovation Organization**

? How sensible is it to waive patents for the production of biologics in the Global South?

! *Imagine Porsche released its patents for Sudan, but the problem is that nobody in Sudan can build a Porsche. Transferred to biopharmaceuticals, this means that most countries will not be able to produce COVID-19 vaccines.*

The US is one of the over 100 countries currently in favour of the waiver, and many NGOs also support it, among them Médecins Sans Frontières (MSF). "In the year that has passed since India and South Africa first tabled the landmark TRIPS Waiver in an effort to increase access to COVID-19 medical tools, tragically over 3.6 million people have died from COVID-19," emphasised MSF vaccine expert Dr Sharmila Shetty in October. In the same press release, the organisation states that political pressure must be put on mRNA vaccine

›› **Read the full story in the printed issue.**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FREE EXCERPT

(Bio)roads to zero

THEMA The climate wasn't saved at COP26 in Glasgow. Many of the state representatives assembled at the conference did, however, agree to a range of diverse constellations for more climate-friendly action, though sometimes the agreements are quite small scale. They also often sound more like declarations of intent, with little in the way of concrete, binding roadmaps. Still, a lot is going on with climate change mitigation, and biotechnology is playing an increasingly important role in the field.

The climate situation is urgent. To understand why, you first have to grasp a few key facts. The first is that to keep global warming under 1.5-2°C, as laid down in the 2015 Paris Agreement, concentrations of long-lived greenhouse gases have to be stabilised at 450 ppm (parts per million) CO_2 equivalents by the end of the century. They're currently hovering around 500 ppm. It's estimated that before the Industrial Revolution, they averaged around 280 ppm. According to the Intergovernmental Panel on Climate Change (IPCC), the only way to hit Paris Agreement goals is to set maximum global emissions limits of 420 billion tonnes of CO_2 equivalents (gigatons of CO_2, $GtCO_2$). At current emissions levels, we'll hit that within eight years. And even in those eight years, we can't count on steady, 'business-as-usual' levels, as some countries have to first increase current emissions in order to be able to reduce them later. So other countries will have to help make up the shortfall, which will be impossible without actively removing CO_2 from the cycle.

At first glance, Europe's footprint actually seems pretty moderate. The entire European Union emits about 3.6 $GtCO_2$ annually. That number, however, doesn't include emissions generated elsewhere by the bloc's global production chains, which would cause it to balloon dramatically. So there's a clear need for technology that can trailblaze new paths in areas like CO_2 capture and sequestration, the move to a circular economy, and replacing fossil hydrocarbons in fuels. A lot is going on, and a lot of it involves cutting-edge biotech methods and platforms.

The many faces of mitigation

There are a number of approaches to the issue of CO_2 removal. One is exemplified for instance by the Lowering Emissions by Accelerating Forest finance (LEAF) Coalition, an alliance of major companies, organisations and countries established in April. Its focus is on protecting forests and massive reforestation programmes. The coalition's goal is to halt deforestation by financing large-scale tropical forest protection. In 2021, it mobilised US$1bn in financing, kicking off the largest ever public-private effort to protect tropical forests. Companies like Amazon, Blackrock, EY, GSK, Airbnb, Unilever, SAP and many others have joined.

Also under development are high-tech approaches for capturing CO_2 for use as building blocks (CCU) directly at production facilities, with many projects receiving funding from various sources in Europe alone. In the EU-funded BioRE-CO_2VER project – a consortium of twelve companies, research institutions and universities coordinated by the NOVA Institute and Flemish research organisation VITO – the partners are investigating technical challenges to the energy-efficient and sustainable biochemical conversion of CO_2. Their approach focuses on the technical perspectives, for example how to design a high-pressure fermenter that can transform CO_2 from industrial sources like refineries and cement plants into useful chemical building blocks such as isobutene or lactate. To overcome some of the existing technical and economic barriers to CO_2 conversion through industrial biotechnology, VITO's new facility focuses on maximising gas transfer in bioreactors and improving scalability.

After years of research, a fermenter is now up and running. With a maximum pressure of 10 bar, the bioreactor allows "incredible flexibility in experimental conditions," says Wouter Van Hecke, a researcher at VITO. "This allows us to study fermentation under a wide range of conditions. We can also use a variety of gas mixtures supplied by companies. In addition, the high-pressure fermenter has a membrane filtration unit to retain the microorganisms in the reactor. This is important to speed up the process and make it more efficient."

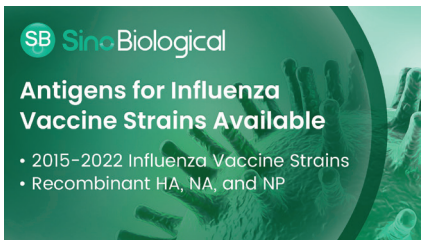
Project manager Heleen De Wever says VITO is trying to better understand the effects of pressure on fermentation. "At the moment, gas fermentations are still too often characterised by low productivity and low product concentrations. By increasing the pressure, and thus the mass transfer from gas to liquid,

›› Read the full story in the printed issue.

Pictures: Solar Foods

FREE EXCERPT

Influenza Vaccine Strains



ANTIGENS Seasonal flu is a common infectious disease of the respiratory tract caused by influenza virus. There are four types of influenza virus, influenza type A, B, C, and D. The A and B types are of most interest to the medical community because they are the culprits for seasonal epidemics. Occasionally, influenza A, like the A/California/04/09 (H1N1) and A/Hong Kong/1/1968 (H3N2), can even cause global pandemics.

Vaccination is the most effective way to prevent flu infection. Each year, several different flu strains are selected as vaccine strains based on surveillance data of the recent isolates, and the performance of the vaccines from the previous season. In recent decades, most vaccines are trivalent or quadrivalent, including one H1N1, one H3N2, and the Yamagata and Victoria type flu B.

Sino Biological offers recombinant Flu antigen products under its ProVir® viral antigen collection. The product line covers HA, NA, and NP proteins, from all WHO-recommended vaccine strains in recent years. These antigens can be used to analyze vaccine-induced antibody response. In addition, Sino Biological also develops a large collection of monoclonal antibodies against the flu antigens. These reagents can help facilitate relevant assay development. ■

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